K120542

JUN - 1 2012

CardinalHealth

1430 Waukegan Road
McGraw Park, IL 60085

www.cardinal.com

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
DuraBlue™ Sterilization Wrap

Manufacturer:	Cardinal Health 200, LLC 1430 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1430 Waukegan Road McGaw Park, IL 60085
Telephone Number:	(847) 887-3323
Date summary Prepared:	March 13, 2012
Trade Name:	DuraBlue™ Sterilization Wrap
Classification:	Class II per 21 CFR § 880.6850
Classification Name:	Sterilization Wrap
Predicate Device:	K082177 - KIMGUARD ONE-STEP Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500 and KC600)

Description:

Cardinal Health DuraBlue™ Sterilization Wraps are double layer sterilization wraps made from 100% polypropylene spunbond-meltblown-spunbond (SMS) fabric. Cardinal Health DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes. The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) for 30 days. The wrap was validated for an aeration time for EO sterilization of 8 hours at 55°C. Models CH400, CH500 and CH600 have been validated for EO sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less. The wrap design allows for use of the simultaneous double-wrapping technique and also allows for a sterilized pack to be opened aseptically.

Cardinal Health DuraBlue™ Sterilization Wrap is the subject of three Premarket Notifications cleared by the FDA—K112211, K112283 and K112918--for use with pre-vacuum steam, STERRAD 100S, and V-PRO sterilization modalities respectively. This submission is specifically for the additional indication for use with EO sterilization.

This submission covers six different models of Cardinal Health DuraBlue™ Sterilization Wrap. Each model is made from material of a different basis weight, though all models utilize the same material technology.

Extensive performance testing has been completed on Cardinal Health DuraBlue™ Sterilization Wrap. Successful completion of the sterilization performance tests listed below demonstrated that the wrap both allows for sterilization of the enclosed contents and maintains sterility of the enclosed contents until opened.

Indications for Use:

Cardinal Health DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131 °F/55°Cand 40%-80% relative humidity for 60 minutes. The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed devices for 30 days. The wrap has been validated for an aeration time of 8 hours at 55°C. Models CH400, CH500 and CH600 have been validated for sterilization of two lumens of 3mm diameter or larger and 400mm in length or less.

Cardinal Health DuraBlue™ Sterilization Wrap is not indicated for use with gravity steam sterilization.

Wrap Model Recommendations[1]

DuraBlue™ Sterilization Wrap Model	**Intended Load**	**Maximum Recommended Wrapped Package Content Weights[2]**
CH100	Very light weight package (for example: towel packs)	3 lbs
CH200	Light weight package (for example: standard linen packs)	6 lbs
CH300	Light to moderate weight package (for example: general use medical instruments)	9 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs
CH500	Heavyweight package (for example: general use medical instruments)	17 lbs
CH600	Very heavy weight package (for example: general use medical instruments)	25 lbs

The following loads were used in the validation studies:

- **CH100:** 16 huck towels (17 in. x 29 in.).
- **CH200:** 2 huck towels (17 in. x 29 in.), 2 fluid resistant drapes (108 in. x 88 in.), 2.5 lb of metal mass.
- **CH300:** 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.

- **CH400:** 4 stacked tray liners (20 in. x 25 in.) and 7.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH500:** 4 stacked tray liners (20 in. x 25 in.) and 11.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH600:** 4 stacked tray liners (20 in. x 25 in.) and 19.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

Note: The loads used in the validation studies corresponded to the maximum wrapped package content weights in the table.

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.
[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight and size of individual content types that were validated for the Cardinal Health DuraBlue™ Sterilization Wrap (i.e., the number and size of the fluid resistant linens or the weight of the metal mass).

Substantial Equivalence

The DuraBlue™ Sterilization Wrap is substantially equivalent to the predicate devices.

- Both devices are double layer sterilization wraps which allow for use of the simultaneous double-wrapping technique and for a sterilized pack to be opened aseptically.
- Both devices are intended to be used with the same 100% ethylene oxide sterilization parameters.
- Both devices are available in six comparable models of varying basis weights, which are recommended for use with the same maximum content weights.
- Both devices have the same dimensional specifications.
- Both devices are100% polypropylene spunbond-meltblown-spunbond (SMS) trilaminate nonwoven fabric.
- Both devices demonstrate maintenance of package sterility until opened following sterilization by100% ethylene oxide.
- Performance and safety attributes are substantially equivalent to the predicate. The physical properties of all wrap models have been characterized both before and after exposure to 100% ethylene oxide sterilization. The resulting data supports the conclusion that Cardinal Health DuraBlue™ Sterilization Wrap is substantially equivalent to the predicate, and the DuraBlue™ Sterilization Wraps are compatible with the identified 100% ethylene oxide sterilization parameters.

Summary of Testing

DuraBlue™ Sterilization Wrap performance has been tested in accordance with the applicable requirements recommended in the FDA's Guidance Document Premarket Notification 510(k) Submissions for Medical Sterilization Packaging System in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002). Testing included sterilization efficacy, event related maintenance of package sterility, physical properties, EO residuals and biocompatibility in compliance with the methods of ISO 10993. Data from testing demonstrates that the performance of the DuraBlue™ Sterilization Wrap is substantially equivalent to that of Kimberly-Clark KIMGUARD ONE-STEP Sterilization Wrap.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cardinal Health-Medical Products and Services
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, Illinois 60062

JUN -6 2012

Re: K120542
Trade/Device Name: Cardinal Health DuraBlue™ Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: May 16, 2012
Received: May 17, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

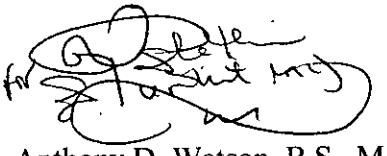
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

Indications for Use

510(k) Number (if known): K120542

Device Name: Cardinal Health DuraBlue™ Sterilization Wrap

Ethylene Oxide Sterilization

Indications for Use:

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Cardinal Health DuraBlue™ Sterilization Wrap is not indicated for use with gravity steam sterilization.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Elizabeth D. Claverie-Wells

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120542

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